## Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

## **Listing of Claims:**

- (Currently Amended) A method of delivery to the pulmonary system comprising:
  administering to the respiratory tract of a patient in need of treatment,
  prophylaxis or diagnosis an effective amount of a dry powder comprising:
- a) a multivalent metal cation which is complexed with a therapeutic, prophylactic or diagnostic agent;
- b) a pharmaceutically acceptable carrier; and
- c) optionally, a multivalent metal cation-containing component wherein, the dry powder is spray-dried and has a total amount of multivalent metal cation which is more than 1% w/w of the total weight of the agent, a tap density of less than about 0.4 g/cm³, a median geometric diameter of from about 5 micrometers and about 30 micrometers and an aerodynamic diameter of from about 1 to about 5 microns. optionally, a multivalent metal cation-containing component wherein, the total amount of multivalent metal cation present in the dry powder is more than 1 % w/w of the total weight of the agent and wherein release of the agent is sustained.
- 2. (Original) The method of Claim 1, wherein the biologically active agent is a protein.
- 3. (Original) The method of Claim 2, wherein the protein is insulin.
- 4. (Original) The method of Claim 2, wherein the multivalent metal cation is selected from Zn(II), Ca(II), Cu(II), Ni(II), Co(II), Fe(II), Ag(II), Mn(II), Mg(II) or Cd(II).

- 5. (Original) The method of Claim 4, wherein the multivalent metal cation is Zn(II).
- 6. (Original) The method of Claim 2, wherein the multivalent metal cation is present at a ratio of more than about 2% w/w of the total weight of the agent.
- 7. (Original) The method of Claim 2, wherein the multivalent metal cation is present at a ratio of more than about 5% w/w of the total weight of the agent.
- 8. (Original) The method of Claim 2, wherein complexation of the agent and multivalent metal cation comprises a metal coordination.
- 9. (Canceled)
- 10. (Currently Amended) The method of Claim 29, wherein the dry powder has have a tap density less than about 0.1 g/cm<sup>3</sup>.
- 11. (Canceled)
- 12. (Canceled)
- 13. (Currently Amended) The method of Claim <u>2</u>+2, wherein the dry powder <u>has have</u> an aerodynamic diameter of from about 1 to about 3 microns.
- 14. (Currently Amended) The method of Claim <u>212</u>, wherein the dry powder <u>has have</u> an aerodynamic diameter of from about 3 to about 5 microns.

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- 15. (Original) The method of Claim 2, wherein delivery to the pulmonary system includes delivery to the deep lung.
- 16. (Original) The method of Claim 2, wherein delivery to the pulmonary system includes delivery to the central airways.
- 17. (Original) The method of Claim 2, wherein delivery to the pulmonary system includes delivery to the upper airways.
- 18. (Original) The method of Claim 2, wherein the dry powder further comprise a carboxylic acid.
- 19. (Original) The method of Claim 18, wherein the carboxylic acid includes at least two carboxyl groups.
- 20. (Original) The method of Claim 19, wherein the carboxylic acid is citric acid or a salt thereof.
- 21. (Original) The method of Claim 2, wherein the dry powder further comprise an amino acid.
- 22. (Original) The method of Claim 21, wherein the amino acid is hydrophobic.
- 23. (Original) The method of Claim 22, wherein the hydrophobic amino acid is leucine, isoleucine, alanine, valine, phenylalanine or any combination thereof.
- 24. (Original) The method of Claim 2 wherein the pharmaceutically acceptable carrier is a phospholipid.

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25. (Original) The method of Claim 24 wherein the phospholipid is a phosphatidic acid, a phosphatidylcholine, a phosphatidylalkanolamine, a phosphatidylethanolamine, a phosphatidylglycerol, a phosphatidylserine, a phosphatidylinositol or combinations thereof.

- 26. (Currently Amended) A method of delivery to the pulmonary system comprising: administering to the respiratory tract of a patient in need of treatment, prophylaxis or diagnosis an effective amount of a dry powder comprising:
  - a) a protein which is complexed with zinc;
  - b) a pharmaceutically acceptable carrier; and
  - c) optionally, a multivalent metal cation-containing component wherein, the dry powder is spray-dried and has a total amount of multivalent metal cation which is more than 2 % w/w of the total weight of the agent, a tap density of less than about 0.4 g/cm³, a median geometric diameter of from about 5 micrometers and about 30 micrometers and an aerodynamic diameter of from about 1 to about 5 microns. optionally, a multivalent metal cation containing component wherein, the total amount of multivalent metal cation present in the dry powder is more than about 2 % w/w of the total weight of the agent, delivery includes the deep lung and release of the agent is sustained.
- 27. (Currently Amended) The method of Claim 26, wherein the dry powder has a tap density less than about 0.1g/cm<sup>3</sup>-and a median geometric diameter of from about 5 micrometers and about 30 micrometers.
- 28. (Original) The method of Claim 26, wherein the pharmaceutically acceptable carrier is a phospholipid.
- 29. (Original) The method of Claim 26 wherein the dry powder further comprises a carboxylic acid.

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30. (Previously Amended) A composition for delivery to the pulmonary system comprising:

- a) an effective amount of dry powder of a therapeutic, prophylactic or diagnostic agent which are complexed to a multivalent metal cation wherein the agent has a charge which is opposite to that of the cation;
- b) a pharmaceutically acceptable carrier; and
- c) optionally, a multivalent metal cation-containing component wherein, the dry powder is capable of being delivered to the pulmonary system and has a total amount of multivalent metal cation which is more than 1 % w/w of the total weight of the agent, a tap density of less than about 0.4 g/cm<sup>3</sup>, a median geometric diameter of from about 5 micrometers and about 30 micrometers and an aerodynamic diameter of from about 1 to about 5 microns.
- 31. (Original) The composition of Claim 30, wherein the biologically active agent is a protein.
- 32. (Original) The composition of Claim 31, wherein the protein is insulin.
- 33. (Original) The composition of Claim 30 wherein the multivalent metal cation is selected from Zn(II), Ca(II), Cu(II), Ni(II), Co(II), Fe(II), Ag(II), Mn(II), Mg(II) or Cd(II).
- 34. (Original) The composition of Claim 33, wherein the multivalent metal cation is Zn(II).
- 35. (Original) The composition of Claim 30, wherein the multivalent metal cation is present at a ratio of more than about 2% w/w of the total weight of the agent.
- 36. (Original) The composition of Claim 30, wherein the multivalent metal cation is present at a ratio of more than about 5% w/w of the total weight of the agent.

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- 37. (Original) The composition of Claim 30, wherein complexation of the agent and multivalent metal cation comprises a metal coordination.
- 38. (Original) The composition of Claim 30, wherein the dry powder have a tap density less than about 0.1 g/cm<sup>3</sup>.
- 39. (Original) The composition of Claim 30, wherein the dry powder have an aerodynamic diameter of from about 1 to about 3 microns.
- 40. (Original) The composition of Claim 30, wherein the dry powder have an aerodynamic diameter of from about 3 to about 5 microns.
- 41. (Original) The composition of Claim 30 wherein the dry powder further comprise a carboxylic acid.
- 42. (Original) The composition of Claim 41, wherein the carboxylic acid includes at least two carboxyl groups.
- 43. (Original) The composition of Claim 42, wherein the carboxylic acid is citric acid or a salt thereof.
- 44. (Original) The composition of Claim 30, wherein the dry powder further comprise an amino acid.
- 45. (Original) The composition of Claim 44, wherein the amino acid is hydrophobic.
- 46. (Original) The composition of Claim 45, wherein the hydrophobic amino acid is leucine, isoleucine, alanine, valine, phenylalanine or any combination thereof.

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47. (Original) The composition of Claim 30 wherein the pharmaceutically acceptable carrier is a phospholipid.

- 48. (Original) The composition of Claim 47 wherein the phospholipid is a phosphatidic acid, a phosphatidylcholine, a phosphatidylalkanolamine, a phosphatidylethanolamine, a phosphatidylglycerol, a phosphatidylserine, a phosphatidylinositol and combinations thereof.
- 49. (Currently Amended) A composition for delivery to the pulmonary system comprising:

administering to the respiratory tract of a patient in need of treatment, prophylaxis or diagnosis an effective amount of a dry powder comprising:

- a) a protein which is complexed with zinc;
- b) a pharmaceutically acceptable carrier; and
- c) optionally, a multivalent metal cation-containing component wherein, the dry powder is spray-dried and has a total amount of multivalent metal cation which is more than 2 % w/w of the total weight of the agent, a tap density of less than about 0.4 g/cm³, a median geometric diameter of from about 5 micrometers and about 30 micrometers and an aerodynamic diameter of from about 1 to about 5 microns. optionally, a multivalent metal cation-containing component wherein, the total amount of multivalent metal cation present in the dry powder is more than about 2 % w/w of the total weight of the agent, delivery includes the deep lung and release of the agent is sustained.
- 50. (Currently Amended) The method of Claim 49, wherein the dry powder has a tap density less than about 0.1g/cm<sup>3</sup>-and a median geometric diameter of from about 5 micrometers and about 30 micrometers.
- 51. (Original) The method of Claim 49, wherein the pharmaceutically acceptable carrier is a phospholipid.

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52. (Original) The method of Claim 49 wherein the dry powder further comprises a carboxylic acid.